CLAIMS

What is claimed is:

1. A dosage form of dalbavancin for parenteral use comprising:

a sterile, stable, particle-free dalbavancin powder suitable for reconstitution with a pharmaceutically acceptable vehicle; and

a stabilizer,

wherein the dosage form is at a pH of about 3-5.

2. The dosage form of claim 1, wherein the stabilizer comprises sugar.

3. The dosage form of claim 2, wherein the sugar is selected from the group consisting of mannitol, lactose, sucrose, sorbitol, glycerol, cellulose, trehalose, maltose, dextrose, and combinations thereof.

4. The dosage form of claim 1, wherein the stabilizer is mannitol.

5. The dosage form of claim 4, wherein the weight ratio of mannitol: dalbavancin is 1:2.

6. The dosage form of claim 1, wherein the stabilizer is lactose.

7. The dosage form of claim 1, wherein the stabilizer is a mixture of mannitol and lactose.

8. The dosage form of claim 7, wherein the weight ratio of mannitol:lactose:dalbavancin is 1:1:4.

9. The dosage form of claim 8, wherein the pH is 4.5.

10. The dosage form of claim 1, wherein the pH is 3.5.

11. The dosage form of claim 1, wherein the pH is 4.5.

12. A method for treating a bacterial infection in a patient in need thereof, the method comprising the steps of:

providing a therapeutically effective dose of a sterile, stable, particle-free dalbavancin powder and a stabilizer at a pH of about 3-5; and

administering the therapeutically effective dose to the patient in need thereof.

13. The method of claim 12, further comprising administering a single subsequent therapeutically effective dose.

14. The method of claim 13, wherein the single subsequent therapeutically effective dose is administered approximately five to ten days after the initial dose without any intervening dose of dalbavancin.

15. The method of claim 12, further comprising administering multiple subsequent therapeutically effective doses.

16. The method of claim 15, wherein the subsequent therapeutically effective doses are administered at approximately five to ten day intervals without any intervening doses of dalbavancin.

17. The method of claim 12, wherein the therapeutically effective dose includes an amount of dalbavancin sufficient to provide a therapeutically effective plasma level of at least about 20 mg of dalbavancin per liter of plasma in the patient for at least five days.

18. The method of claim 12, wherein the therapeutically effective dose includes an amount of dalbavancin sufficient to provide a therapeutically effective plasma level of at least about 30 mg of dalbavancin per liter of plasma in the patient for at least five days.

19. The method of claim 12, wherein the therapeutically effective dose achieves a patient exposure (area under the curve) of at least 19844 mg•h/L.

20. The method of claim 12, wherein the therapeutically effective dose includes an amount of dalbavancin sufficient to provide a bactericidal plasma level for at least about five to about ten days.

21. The method of claim 20, wherein the bactericidal plasma level is at least about 20 mg/L.

22. The method of claim 20, wherein the bactericidal plasma level is at least about 30 mg/L.

23. The method of claim 12, wherein the therapeutically effective dose achieves a peak concentration in the patient (C_{max}) of at least 243 mg/L.

24. The method of claim 12, wherein the therapeutically effective dose achieves a peak concentration in the patient (C_{max}) of approximately 300 mg/L.

25. A dosage form of dalbavancin for parenteral use comprising:

a sterile, stable, particle-free dalbavancin powder suitable for reconstitution with a pharmaceutically acceptable vehicle and mannitol at a pH of about 3-5.

26. The dosage form of claim 25, wherein the pharmaceutical composition further comprises lactose.

27. The dosage form of claim 25, wherein the pH is about 3.5.

28. A method for treating a bacterial infection in a patient in need thereof, the method comprising the steps of:

providing a therapeutically effective dose of a particle-free, sterile dalbavancin powder and mannitol at a pH of about 3-5, and

administering the therapeutically effective dose to the patient in need thereof.

29. The method of claim 28, further comprising administering a single subsequent therapeutically effective dose.

30. The method of claim 29, wherein the single subsequent therapeutically effective dose is administered approximately five to ten days after the initial dose without any intervening dose of dalbavancin.

31. The method of claim 28, further comprising administering multiple subsequent therapeutically effective doses.

32. The method of claim 31, wherein the subsequent therapeutically effective doses are administered at approximately five to ten day intervals without any intervening doses of dalbavancin.

33. A pharmaceutical composition comprising:

dalbavancin; and

a stabilizer, wherein the stabilizer comprises mannitol and lactose.

34. The pharmaceutical composition of claim 33, wherein the weight ratio of mannitol:lactose:dalbavancin is 1:1:4.

35. The pharmaceutical composition of claim 33, wherein the pharmaceutical composition has a pH of about 3 to 5.

36. The pharmaceutical composition of claim 33, wherein the pharmaceutical composition has a pH of about 4.5.

37. A method for treating a bacterial infection in a patient in need thereof, the method comprising the steps of:

providing a therapeutically effective doses of a pharmaceutical composition comprising dalbavancin and a stabilizer comprising mannitol and lactose; and

administering the therapeutically effective dose to the patient in need thereof.

38. The method of claim 37, further comprising administering a single subsequent therapeutically effective dose.

39. The method of claim 38, wherein the single subsequent therapeutically effective dose is administered approximately five to ten days after the initial dose without any intervening dose of dalbavancin.

40. The method of claim 37, further comprising administering multiple subsequent therapeutically effective doses.

41. The method of claim 40, wherein the subsequent therapeutically effective doses are administered at approximately five to ten day intervals without any intervening doses of dalbavancin.

42. The method of claim 37, wherein the pharmaceutical composition has a pH of about 3 to 5.

43. The method of claim 38, wherein the pharmaceutical composition has a pH of about 4.5.

44. A pharmaceutical composition comprising:

dalbavancin and a stabilizer.

45. The pharmaceutical composition of claim 44, wherein the stabilizer comprises a sugar.

46. The pharmaceutical composition of claim 45, wherein the sugar is selected from the group consisting of mannitol, lactose, sucrose, sorbitol, glycerol, cellulose, trehalose, maltose, dextrose, and combinations thereof.

47. The pharmaceutical composition of claim 44, wherein the stabilizer is mannitol.

48. The pharmaceutical composition of claim 47, wherein the weight ratio of mannitol:dalbavancin is 1:2.

49. The pharmaceutical composition of claim 44, wherein the stabilizer is lactose.

50. The pharmaceutical composition of claim 44, wherein the stabilizer is a mixture of mannitol and lactose.

51. The pharmaceutical composition of claim 50, wherein the weight ratio of mannitol:lactose:dalbavancin is 1:1:4.

52. The pharmaceutical composition of claim 44, wherein the pharmaceutical composition has a pH of about 3-5.

53. The pharmaceutical composition of claim 44, wherein the pharmaceutical composition has a pH of about 4.5.

54. A method for treating a bacterial infection in a patient in need thereof, the method comprising the steps of:

providing a therapeutically effective dose of a pharmaceutical composition comprising dalbavancin and a stabilizer; and

administering the therapeutically effective dose to the patient in need thereof.

55. The method of claim 54, further comprising administering a single subsequent therapeutically effective dose.

56. The method of claim 55, wherein the single subsequent therapeutically effective dose is administered approximately five to ten days after the initial dose without any intervening dose of dalbavancin.

57. The method of claim 54, further comprising administering multiple subsequent therapeutically effective doses.

58. The method of claim 57, wherein the subsequent therapeutically effective doses are administered at approximately five to ten day intervals without any intervening doses of dalbavancin.

59. The method of claim 54, wherein the therapeutically effective dose includes an amount of dalbavancin sufficient to provide a therapeutically effective plasma level of at least about 20 mg of dalbavancin per liter of plasma in the patient for at least five days.

60. The method of claim 54, wherein the therapeutically effective dose includes an amount of dalbavancin sufficient to provide a therapeutically effective plasma level of at least about 30 mg of dalbavancin per liter of plasma in the patient for at least five days.

61. The method of claim 54, wherein the therapeutically effective dose achieves a patient exposure (area under the curve) of at least 19844 mg•h/L.

62. The method of claim 54, wherein the therapeutically effective dose includes an amount of dalbavancin sufficient to provide a bactericidal plasma level for at least about five to about ten days.

63. The method of claim 62, wherein the bactericidal plasma level is at least about 20 mg/L.

64. The method of claim 62, wherein the bactericidal plasma level is at least about 30 mg/L.

65. The method of claim 54, wherein the therapeutically effective dose achieves a peak concentration in the patient (C_{max}) of at least 243 mg/L.

66. The method of claim 54, wherein the therapeutically effective dose achieves a peak concentration in the patient (C_{max}) of approximately 300 mg/L.